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| APPLICATION NO | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO | CONFIRMATION NO |
|----------------|-------------|----------------------|--------------------|-----------------|
| 09 737,687     | 12 14 2000  | Darin Arthur Allen   | 218                | 1550            |

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Axys Pharmaceuticals, Inc.  
180 Kimball Way  
South San Francisco, CA 94080

EXAMINER

WRIGHT, SONYA N

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1626

DATE MAILED: 12 05 2001

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/737.687

Applicant(s)

ALLEN ET AL

Examiner

Sonya Wright

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 18-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☒ Claim(s) 2-8 and 10-17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other

### DETAILED ACTION

Claims 1-31 are pending in this application.

#### ***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-8 and 10-17 and the species of page 66, line 8 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that if, in order to comply with the Restriction Requirement, the Applicants are compelled to divide their generically claimed invention into various subgenus claims, the Applicants will not have their claims examined in the form that they believe to best define their invention.

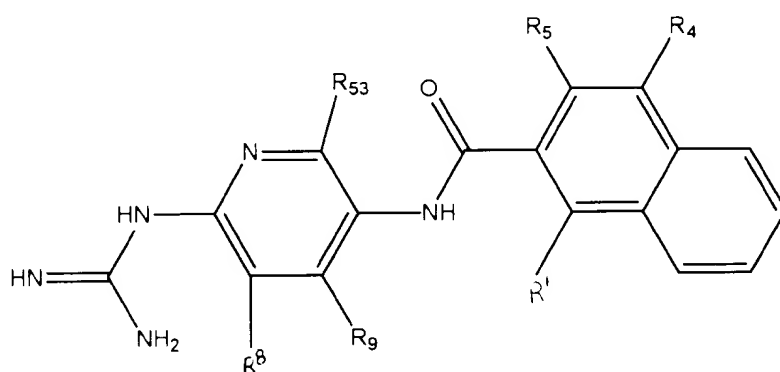
This is not found persuasive because Groups I-III supra are distinct, each from the other, because they differ in structure and/or element so as to be patentably distinct, and a prior art reference anticipating but one of the groups would not render obvious the other groups under 35 U.S.C. 103 (MPEP 806.04(f)). Each group is capable of supporting its own patent. Examination of more than one of the above groups would be an undue burden as it would require additional search in both the patent and non-patent literature.

Claims 1-31 are generic to a plurality of disclosed patentably distinct species comprising for example, the compounds of examples 150, 167, 174, etc. . . . Therefore, it is necessary for a subgeneric concept, inclusive of the elected species, to be carved out of generic claim 1. A search of Applicants invention includes a search of patent literature in classes, and of patent and non-patent literature in computer databases. A

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severe burden would be imposed on the examination of this application if a subgeneric concept were not carved out.

The subgeneric concept is as depicted in claim 1, wherein the compound of Formula I is:



and R<sup>1</sup>, R<sup>4</sup>, R<sup>5</sup>, R<sup>8</sup>, R<sup>9</sup>, and R<sup>53</sup> are as defined in claim 1, except that R<sup>4</sup> and R<sup>5</sup> cannot be taken together to form a ring, and R<sup>6</sup> and R<sup>53</sup> cannot be taken together to form a ring, ( R<sup>6</sup> is no longer a variable of formula 1). All of the above are identified for examination along with the elected embodiment. The remaining subject matter of claims 1-8 and 10-17 and the subject matter of claims 9 and 18-31 stands withdrawn from further consideration under 37 CFR 1.142(b) as constituting other patentably distinct inventions.

The withdrawn subject matter of claims 1-8 and 10-17 properly restricted as said subject matter differs in structure and element from the elected subject matter so as to

be patentably distinct therefrom, i.e. a reference which anticipated the elected subject matter would not even render obvious the withdrawn subject matter and fields of search are not co-extensive.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-8 and 10-17 are objected to as containing non-elected subject matter. This objection may be overcome by limiting the claims to the elected subject matter identified supra.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, page 58, line 9, the term "pharmaceutically acceptable salts" should be changed to —a pharmaceutically acceptable salt—for proper claim language.

In claim 1, page 62, lines 1-2, Q, Q1, Q2, Q3, L1, L2, L3, and L4 may each represent an "unnatural amino acid side chain". The term "unnatural amino acid side chain" embraces a plethora of compounds. Applicant has not indicated which "unnatural amino side chain(s)" are included in the invention. Therefore, the claim is rendered indefinite. Appropriate correction is necessary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-

4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.


Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.

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Taofiq Solola, Ph.D.

Primary Examiner

Group 1600

Sonya Wright

November 27, 2001